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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,162	10/03/2006	Hughes Jaccard	CV-E-006-PUS	6061
28986	7590	03/10/2011	EXAMINER	
HARRIET M. STRIMPEL, D. Phil.			BERCH, MARK L	
New England Biolabs, Inc.				
240 COUNTY ROAD			ART UNIT	PAPER NUMBER
IPSWICH, MA 01938-2723			1624	
			NOTIFICATION DATE	DELIVERY MODE
			03/10/2011	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/591,162	<b>Applicant(s)</b> JACCARD ET AL.
	<b>Examiner</b> Mark L. Berch	<b>Art Unit</b> 1624

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02/25/2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-11,14-22 and 44-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-11,14-22 and 44-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)<br>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)<br>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____.<br>5) <input type="checkbox"/> Notice of Informal Patent Application<br>6) <input type="checkbox"/> Other: _____. |
|---|--|

### DETAILED ACTION

Prosecution is reopened; the most recent amendment is entered.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4-11, 14-22, and 44-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. In next to last line of claim 1, the “capable” is unclear. Does it modify just “derivative” or does it modify “nucleic acid” as well. The wording could be read either way.
2. In addition, the term “derivative” (or a nucleic acid) is inherently indefinite, since one does not know how much modification is permitted and the material still qualifies as a nucleic acid derivative. Derivatives called artificial nucleic acids including peptide nucleic acid (PNA), locked nucleic acid (LNA), glycol nucleic acid (GNA) and threose nucleic acid (TNA), which have changes to the backbone, are these included? What about the morpholinos (PMO)?
3. In R6, “substituted amino” is indefinite. The specification provides no guidance on the scope of this term. What qualifies as a “substituted” amino? For example, groups such as the carboxamido (e.g. acetamido), sulfonamido (e.g. methanesulfonamido), nitro, isocyano, nitrosyl, hydrazino, azido, diazonium ( $-N_2^+$ ) and quaternary ammonium (e.g.  $-N(\text{methyl})_3^+$ ) among monovalent choices and diazo ( $=N_2$ ) or imino

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(e.g.=NH, where the = is either one double bond, or two single bonds to adjacent carbons to form a three membered C<sub>2</sub>N ring) for divalent choices are sometimes not thought of, or named, as being substituted amino but could be viewed as a substituted amino with a sufficiently broad definition of what is a substituent.

Which of these are and which are not included, and how would one of ordinary skill in the art know this, given the lack of guidance in the specification on this matter?

Could the N be part of a ring?

4. The “moiety covalently attached to a solid support” is unclear. What is the nature of the moiety itself? All this says is that one of the L1 is a solid support, but what is the rest of it?
5. In addition, Claim 45 provides for L2 itself being the solid support, but claim 1 actually has L2 as being “moiety covalently attached to a solid support”, not solid support itself. This makes it unclear what is intended for L2: is it a moiety capable of binding to a solid support, or is it the solid support itself?
6. Claims 10 and 11 do not seem correct. Claim 10 permits one or both of L1 and L2 to be a quencher, and claim 11 requires that exactly one of them be a quencher.

However, while a fluorophore is provided for as a choice, a quencher is not. And note that claim 10 permits a quencher with no fluorophore and vice versa; it is unclear whether that is really intended. This issue affects claim 46 as well.

### *Claim Objections*

Claim 7 is objected to as unduly multiplied. Claim 7 is an exact duplicate of claim 6.

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*Specification*

Boxes appear on page 4 and 8 and possibly elsewhere in place of a Greek letter, and on page 8 for a triple bond.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663.

The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark L. Berch/  
Primary Examiner  
Art Unit 1624

3/7/2011